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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,265	11/14/2003	Nadine Ferdman Burton	051438-5002	8062
9629	7590	01/24/2006	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			HILL, LAURA C	
			ART UNIT	PAPER NUMBER

3761

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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10-712-265

EXAMINER
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ART UNIT	PAPER
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20060118

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner for Patents**

## Office Action Summary

Application No.

10/712,265

Applicant(s)

BURTON ET AL.

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/16 & 12/29/05.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 20050721.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. It is noted that the documents FR 1,077,898 and EP 0150666 submitted in the IDS filed 16 February 2005 have been considered in pursuant to 37 CFR 1.98 and MPEP 609.04(a).

### ***Drawings***

2. All objections to the drawings made in the previous Office Action have been removed.

### ***Claim Objections***

3. All objections to the claims made in the previous Office Action have been removed.

### ***Claim Language Interpretation***

4. It is noted that the 'actuator' of claim 1 is interpreted to be buttons 206 or any other mechanism that collapses/closes the fluid passage of conduit 283 as recited in page 2 of the specification.

### ***Response to Arguments***

5. Applicant's arguments, see pages 12-14 of Remarks, filed 28 November 2005, with respect to the rejection(s) of claim(s) 1-2 under 35 USC 102(b) by Kreb, claims 1-3 and 9 under 35 USC 102(b) by Lee, claim 4 under 35 USC 103(a) over Lee, and claims 5-8 and 10-24 under 35 USC 103(a) over Lee in view of Imonti have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

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However, upon further consideration, a new ground(s) of rejection is made in view of Imonti (US 5,098,416) as discussed below.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-7, and 9-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Imonti (US 5,098,416; herein 'Imonti'). Regarding claims 1, 15 and 20 Imonti discloses a medical grade plastic aspiration device 12 with an aspiration cylinder 12, a removable fluid conduit 26 having a first end for attaching to aspiration cylinder 12 and a second end for attaching to cannula 34, and a body portion/valve housing 28 having first housing 30 attached to second housing portions 32 via releasable connector latch 40 that define a cavity 16 for removably holding a portion of fluid conduit 26(column 4, lines 9-15, figure 2), and vacuum stop/clamp actuator 46 which maintains a vacuum within cavity 16 and prevents body fluid leaking, and thus is capable of compressing the fluid conduit 16 open and closing a fluid path (column 5, lines 1-6).

Regarding claims 2-3 Imonti discloses first housing portion is finger grip 30 and second housing is the end nearest open-end portion 32 comprises a single-piece plastic unit (column 4, lines 20-27 and figures 1-2).

Regarding claims 5-7 Imonti discloses a resilient tubing/first receptacle 17 for receiving an end of aspiration cylinder 12 to provide a sealed connection between the

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fluid conduit 26 and aspirator assembly 12 and wherein the conduit 26 and receptacle are integrally formed such that the fluid passageway extends continuously through the conduit 26 (column 3, lines 23-32 and 44-55 and figure 1).

Regarding claims 9 and 12 Imonti discloses first and second housing portions 30,32 engage fluid conduit 26 to restrain fluid movement relative to the housing (figure 2).

Regarding claims 10-11 and 24 Imonti discloses luer type adapter/cap 42 that connects to first and second housing portions 30,32 and extends over a portion of fluid conduit 26 (column 4, lines 39-42 and figures 1-2) and a portion of fluid conduit 26 that extends outwardly from an end of housing 26 (portion 44 that extends beyond housing portion 30 in figure 2).

Regarding claims 13-14 Imonti discloses integrally formed hollow tip/sealing receptacle 18 that provides a seal between aspiration cylinder 12 and fluid conduit 26 (column 3, lines 55-56 and figure 1).

Regarding claims 16-19 Imonti discloses a double living hinge formed by pin 54 which causes the first housing portion 30 to pivot relative to second housing portion 32 (column 4, lines 47-54 and figure 1).

Regarding claims 21-23 Imonti discloses releasable latch 40 comprises a syringe locking device/latch tab 44 (column 4, lines 38-42) with integrally formed recesses and a dome portion/indented sides (figure 1).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 4 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imonti (US 5,098,416; herein 'Imonti') in view of Bayard (US 4,366,816; herein 'Bayard'). Imonti discloses the assembly can be made of autoclavable plastic for reuse (column 5, lines 31-36). Imonti *does not expressly disclose* the medical grade plastic is polypropylene or silicone. It is well known that polypropylene and silicone are medical grade plastics that can be sterilized as supported by Bayard (column 5, line 67-column 6, line 13). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the sterilizable medical grade plastic housing of Imonti to include any type of medical grade plastic such as polypropylene and silicone, thus providing the aforementioned medical grade plastics that can be sterilized.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imonti (US 5,098,416; herein 'Imonti') in view of Beuchat (US 5,041,096; herein 'Beuchat'). Imonti *does not expressly disclose* resilient tubing/first receptacle 17 comprises silicone. **Beuchat** discloses is known to use flexible tubing 20 for aspirating comprises silicone (column 4, lines 46-55). One would be motivated to modify the resilient tubing of Imonti

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with the silicone of Beuchat to provide a flexible and sterilizable tubing mechanism since both references disclose aspirating systems. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the resilient tubing and thus providing tubing comprising silicone.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schraga (US 5,518,004) is cited for showing reusable plastic specimen drawing device 10 comprising removable fluid conduit 20 having a second end for attaching to a cannula 31 and a push release member/actuator 50 that pushes protective shield 40 from its engaged position about the tubular housing 20 and disengaging the cannula assembly 30. Sagstetter et al. (US 5,219,333) is cited for showing blood collection tube holder 10 with removable fluid conduit 12 and end attached to cannula 42 and tab 42 coupled to valve housing 22 for stabilizing insert. Lee (US 5,115,816) is cited for showing a plastic single-hand aspirating device 10 with removable syringe barrel/fluid conduit 12 with second end for attaching to cannula 11 but no separate aspiration cylinder and finger grip means 40 for attaching to fluid conduit 12. Hauze (US 4,813,931) is cited for showing pediatric suction system 10 with plastic suction tube 26 and a valve with second housing portion 12 and first housing portion 16 and cap 64 but no actuator. Bonaldo (Re 35,539) is cited for showing a blood collection device 10 with medical grade polypropylene barrel/conduit 12 and needle 22 mounted on disk 24 of barrel 12.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill  
Examiner  
Art Unit 3761

LCH

LC97

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER



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